

## Food and Drug Administration, HHS

## § 660.55

been shown to yield consistently a specific, potent final product, free of properties that would adversely affect the product for its intended use throughout its dating period.

(2) Anti-IgG, -C3d (polyspecific) reagents and anti-IgG products may be colored green.

(3) Only that material which has been fully processed, thoroughly mixed in a single vessel, and filtered shall constitute a lot. Each lot shall be identified by a lot number.

(4) A lot may be subdivided into sublots which shall be identified by the lot number to which has been added a distinctive prefix or suffix. If lots are to be subdivided, the manufacturer shall include this information in the license application. The manufacturer shall describe the test specifications to verify that each subplot is identical to other sublots of the lot.

(b) *Final containers and dropper assemblies.* (1) Final containers and dropper assemblies shall be clean.

(2) Final containers and dropper pipettes shall be colorless and sufficiently transparent to permit observation of the contents for presence of particulate matter or increased turbidity.

(c) *Date of manufacture.* The date of manufacture shall be the date the manufacturer begins the last entire group of potency tests.

[50 FR 5579, Feb. 11, 1985, as amended at 50 FR 16474, Apr. 26, 1985; 65 FR 77499, Dec. 12, 2000; 67 FR 9587, Mar. 4, 2002]

### § 660.52 Reference preparations.

Reference Anti-Human Globulin preparations shall be obtained from the Center for Biologics Evaluation and Research (HFM-407) (see mailing addresses in §600.2 of this chapter), and shall be used as described in the accompanying package insert for determining the potency of Anti-Human Globulin.

[50 FR 5579, Feb. 11, 1985, as amended at 50 FR 16474, Apr. 26, 1985; 51 FR 15611, Apr. 25, 1986; 55 FR 11015, Mar. 26, 1990; 67 FR 9587, Mar. 4, 2002; 70 FR 14986, Mar. 24, 2005]

### § 660.53 Controls for serological procedures.

Red blood cells sensitized with complement shall be tested with appropriate positive and negative control

antisera. All tests shall be performed in accordance with serological testing procedures approved by the Director, Center for Biologics Evaluation and Research.

[50 FR 5579, Feb. 11, 1985, as amended at 50 FR 16474, Apr. 26, 1985; 51 FR 15611, Apr. 25, 1986; 55 FR 11014, Mar. 26, 1990; 67 FR 9587, Mar. 4, 2002; 70 FR 14986, Mar. 24, 2005]

### § 660.54 Potency tests, specificity tests, tests for heterospecific antibodies, and additional tests for nonspecific properties.

The following tests shall be performed using test procedures approved by the Director, Center for Biologics Evaluation and Research:

(a) Potency tests for determining anti-IgG and anti-complement activity.

(b) Specificity tests, tests for heterospecific antibodies, and additional tests for nonspecific properties.

[50 FR 5579, Feb. 11, 1985, as amended at 50 FR 16474, Apr. 26, 1985; 51 FR 15611, Apr. 25, 1986; 55 FR 11014, Mar. 26, 1990; 67 FR 9587, Mar. 4, 2002; 70 FR 14986, Mar. 24, 2005]

### § 660.55 Labeling.

In addition to the applicable labeling requirements of §§610.62 through 610.65 and §809.10 of this chapter, and in lieu of the requirements in §§610.60 and 610.61 of this chapter, the following requirements shall be met:

(a) *Final container label*—(1) *Color coding.* The main panel of the final container label of all Anti-IgG, -C3d (polyspecific) reagents shall be white or colorless and printing shall be solid dark contrasting lettering. The main panel of the final container label of all other Anti-Human Globulin reagents shall be black with solid white lettering. A logo or company name may be placed on the final container label, however, the logo or company name shall be located along the bottom or end of the label, outside of the main panel.

(2) *Required information.* The proper name “Anti-Human Globulin” need not appear on the final container label provided the final container is distributed in a package and the package label bears the proper name. The final container label shall bear the following information: